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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/727,633	11/15/96	SAMARITANI	

08/727,633 11/15/96 SAMARITANI

EXAMINER
F/42-60

HM11/0911  
OSTROLENK FABER GERB & SOFFEN  
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NEW YORK NY 10036-8403

PAPER NUMBER
FITZGERALD, D

1646  
DATE MAILED:

09/11/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 27 August 1998

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

☒ Claim(s) 1, 3-10 is/are pending in the application  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1, 3-10 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

#### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved  
☒ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

1. The request filed on 27 August 1998 under 37 C.F.R. § 1.53(d) for a Continued Prosecution Application (CPA) based on parent application serial no. 08/737,633 is acceptable. A CPA has been established, and an action on the CPA follows.

2. Insofar as the rejections of record are maintained below, applicant's arguments filed 27 August 1998 have been fully considered, but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Substitute pages 2 and 3 of the specification, filed with the reply of 27 August 1998, have been entered and satisfy the requirement therefor (see ¶ 3 of Paper No. 7 and the advisory action mailed 19 March 1998, Paper No. 10). Substitute page 1 has not been entered because it contains the insertion of the word "activity" at line 13 which was not present in the application papers as filed. The requirement for a replacement page 1 is accordingly maintained as previously set forth.

4. The rejection under 35 U.S.C. § 103(a) of claims 1 and 3-10 as unpatentable over Cymbalista '454 as taken in view of Hershenson '605 and Rideout '232 is maintained for the reasons set forth at ¶ 6 of Paper No. 5 and at ¶ 5 of Paper No. 7.

The declaration under 37 C.F.R. § 1.132 filed 27 August 1998 is insufficient to overcome the present rejection because declarant's determinations as to the teachings of the references relied upon, which are questions of fact, are consonant with those of the Office (see the discussion in Paper No. 10) and hence have already been factored into the Office's analysis of the evidence.

Declarant's opinion that the invention would not have been obvious is accorded no evidentiary weight because obviousness under § 103(a) is a conclusion of law, not a finding of fact. The evidence declarant cites a supporting his opinion is, however, relevant and has been considered. Declarant notes, and counsel argues, that the degree of stabilizing effect that any compound identified in the prior art as a "stabilizer" will have cannot be predicted prior to an experimental assessment of the effect. The examiner does not contest this observation but considers that it is not relevant to the claims at issue because they do not require any particular degree of stabilization other than effective "stabilizing." As the prior art expressly teaches that mannitol will be suitable as a stabilizer for IFN- $\beta$ , declarant's observation neither contradicts the teachings of the prior art nor points to any unexpected feature of the invention as claimed.

Declarant also observes that the stabilization effected by a low-pH acetate buffer is greater than that observed with other buffers, and counsel argues that this result is unexpected and hence patentably defines over the prior art. This argument is not persuasive because the prior art expressly teaches that an acetate buffer, pH 3.5, desirably affords a stable IFN- $\beta$  formulation. That other buffers may be less suitable is not probative of unobviousness because the prior art does not teach that other such buffers should be used or that they would function interchangeably with an acetate buffer. Moreover, the acetate buffer as advocated and exemplified in the prior art would necessarily have compared to the other buffers discussed in the present specification in the manner described by applicant, whether or not such comparison was taught in the prior art. The mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Baxter Travenol Labs*, 952 F.2d 388, \_\_\_, 21 USPQ2d 1281, 1295 (Fed. Cir. 1991).

Finally, counsel urges that the silence of the reference as to the use of mannitol alone cannot provide a proper basis for a conclusion of obviousness. This argument is not persuasive because it is not the silence of any reference as to the omission of stabilizers other than mannitol upon which the rejection is based. Rather, in contradistinction to the facts of *In re Burt*, 356 F.2d 115, 148 USPQ 548 (CCPA 1966), and the legal analysis at issue in *In re Newell*, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989), both cited by counsel, it is the express, affirmative teachings in the prior art regarding the suitability of mannitol as a stabilizer for IFN- $\beta$  which the Office here relies upon.

Applicant has neither argued nor provided evidence to suggest that mannitol by itself has any stabilizing property which is different from that suggested by the prior art or that the invention as claimed affords any advantage which is not possessed or suggested by the prior art. It remains the Office's conclusion, based on the evidence of record, that the invention as now claimed would have been obvious to one of ordinary skill in this art.

5. The examiner believes that he has addressed all pertinent arguments. No claim is allowed.

6. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 C.F.R. § 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly,

**THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 C.F.R. § 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

*A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.*

7. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.



DAVID L. FITZGERALD

PRIMARY EXAMINER

ART UNIT 1646

10 September 1998

Examiner Fitzgerald is generally available weekdays from 8 a.m. to 4 p.m. (Eastern). If he is not available to take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the interim supervisor for this Art Unit, Lila Feisee, may be reached at (703) 308-2731.

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